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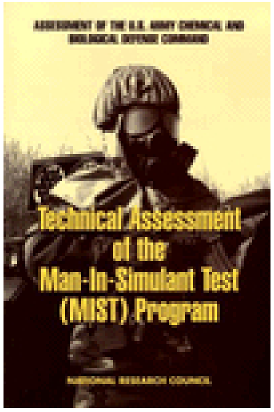

Technical Assessment of the Man-in-Simulant Test Program

Standing Committee on Program and Technical Review of the U.S. Army Chemical and Biological Defense Command, National Research Council

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Executive Summary

In 1993 the U.S. Army established the Chemical and Biological Defense Command (CBDCOM) to conduct research, develop and procure support systems, and design equipment to protect U.S. military personnel from the increasing threat by foreign entities and terrorist organizations to use chemical and biological weapons. CBDCOM is the latest in a long history of military organizations designated for chemical and biological defense research. Because of the critical nature of its mission, the CBDCOM requested that the National Research Council (NRC) establish an oversight committee of nationally recognized experts to provide ongoing, impartial, independent advice and assessments.

The NRC, responding through the Board on Army Science and Technology of the Commission on Engineering and Technical Systems, created a standing committee called the Program and Technical Review of the U.S. Army Chemical and Biological Defense Command, better known as the CBDCOM Standing Committee (CSC). This committee was assembled to provide expertise in the areas of science and technology pertinent to the concerns of the CBDCOM commander and executive director and the technical director of the Edgewood Research, Development and Engineering Center (RDEC), which historically has been an important organization in the Army and Department of Defense for chemical and biological research.

The U.S Army has not established specific requirements for the chemical protective qualities of its ensembles (chemical protective ensembles, or CPEs). This is because test results (protection factors) have never been correlated with biological endpoints. Instead, new CPEs have been evaluated in comparison to the CPE currently in the field (e.g., the battle dress overgarment, BDO). The goal of the Army's program has been to increase chemical protection factors while decreasing undesirable properties (weight and heat stress), although there is no clear understanding of how much chemical protection would be enough to maintain battlefield effectiveness. The man-in-simulant test program (MIST) is responsible for specifying protection factors, but it does not, by itself, link them to biological effects and has not answered the CPE developer's question of how much protection is enough.

The cornerstone of chemical and biological defense strategy is protection (i.e., insulating personnel from chemical and biological agents using individual clothing ensembles and respirators, as well as collective filtration systems and shelters). The CSC was asked by the CBDCOM to undertake a technology assessment of the Army's MIST program—which is designed to test protective suit ensembles in simulated chemical attacks. Specifically, the CSC was asked to:

1. review the test methodology for the man-in-simulant test program[1]
2. review the use of biological markers (e.g., cholinesterase inhibition) to predict the signs and symptoms associated with exposure to nerve (VX) and vesicant (HD) agents
3. review the test methodology for employing passive and active vapor and aerosol samplers during simulant tests at Dugway Proving Ground, Utah, and assess the plan for data collection and analysis
4. determine whether the current chemical simulant, methyl salicylate, or an alternative simulant should be used in the MIST program

To accomplish this task the CSC established a panel of experts from members of the committee to undertake the MIST review. The panel has addressed each item on the list and has summarized the conclusions and recommendations below. The background information and rationale behind these findings are detailed in the full report.

[1] The original statement of task for Task 1 included "and the rationale for using methyl salicylate as a chemical agent simulant in this test program." The committee felt that this aspect of the review was reiterated in Task 4 and has addressed the question there.

TASK 1. Review the test methodology for the man-in-simulant test program.

Conclusion 1. The MIST is a well-designed test protocol for evaluating chemical protective ensembles. However, the committee found that the test methodology was not based on preliminary testing that would eliminate ensembles with gross defects and allow more replications of tests be done on fewer candidate protective ensembles, thereby increasing the statistical power of the results.

Recommendation 1. The Army should screen ensembles prior to a full-blown MIST by video imaging the skin of test subjects after exposure to a fluorescent tracer or other physical tests. Screening should also include variations in ambient conditions (temperature, humidity, wind, and, perhaps, rain), activities (kneeling, sitting, and crawling), and sweat-soaked and dry test challenges.

TASK 2. Review the use of biological markers (e.g., cholinesterase inhibition) to predict the signs and symptoms associated with exposure to nerve (VX) and vesicant (HD) agents.

Conclusion 2. Body region hazard analysis (BRHA) is an innovative approach that takes into account regional variations in skin sensitivity to chemical agents. Although the basic approach is sound, the committee has the following reservations:

- A direct relationship has not been established between cholinesterase depression and the percutaneous absorption of agent.
- The relationship between liquid and vapor absorption has not been determined.
- BRHA was based on the local absorption of VX and may not accurately predict the absorption of HD.
- BRHA does not account for functional impairments from mustard-induced lesions in various body regions.
- BRHA does not account for individual differences in sensitivity to chemical agents.

A direct determinant of the toxicity of a chemical agent is the permeability of the skin by that agent at a given anatomic site.

Therefore, the committee concluded that rather than basing the BRHA on highly variable indirect measures (cholinesterase depression) and assumptions, a protocol should be designed to quantify the *in vitro* agent permeability of excised human skin samples from different body regions. These techniques are well established and well accepted and could also be used to compare simulant uptake by human skin and passive samplers. Large differences may indicate a need to redesign the samplers. The vapor uptake of agent and simulant could also be determined for human skin and passive samplers. Large differences in the behavior of agent and simulant may warrant the selection of a different simulant or adjustments in the methods used to calculate protection factors.

Recommendation 2a. The Army should measure regional variations in skin penetration for HD, VX, and simulant vapors using excised human skin harvested from various anatomic sites.

Recommendation 2b. As a supplemental validation of the systematic BRHA, a biomonitoring protocol should be developed for the MIST, analogous to the protocol used to monitor pesticide exposures to agricultural workers. If the appropriate simulant is used, the calibrations obtained from *in vitro* studies could be used to relate suit performance to physiological effects based on the absorbed dose.

TASK 3. Review the test methodology for employing passive and active vapor and aerosol samplers during simulant tests and assess the data collection and analysis plan.

Conclusion 3. Passive samplers are appropriate means for testing for the presence of vapor. The protocol, however, may not be valid for aerosols because the disposition of chemical agents in aerosol and vapor forms can be quite different. From the information recorded in the documents given to the committee for review, the committee could not confirm the uniformity of simulant concentration within the test chamber. Variations in concentration outside the protective ensemble could lead to errors in assessing the protective qualities of the suit.

Although passive samplers are generally regarded as less accurate than active samplers in bench trials, the differences in the results are small. The precision and accuracy of the Natick sampler is adequate for the intended purpose. The small size of the Natick sampler enables testing under the suit without incurring a number of disadvantages (outlined in Chapter 4) that would be incurred with active sampler pumps either inside or outside the suit.

A residual disadvantage of passive samplers may be a lack of sensitivity to brief variations in concentration, which would be of interest only for identifying the body positions or activities associated with leakage. Conventional active samplers would have the same disadvantage, but external samplers connected to a near-real-time monitor could provide this information.

Recommendation 3. Agent uniformity in all parts of the test chamber throughout the duration of the tests should be documented. In addition, concentrations inside the suit could be monitored with either active or passive samplers, despite their logistical problems. Comparing simulant levels in the passive sampler with samples recovered from the stratum corneum of test subjects (the outermost layer of the skin, which can be removed by repeated applications of adhesive tape) would provide insights into sampler performance.

TASK 4. Determine whether the current chemical simulant, methyl salicylate, or an alternative simulant should be used in the MIST program.

Conclusion 4. Methyl salicylate is an appropriate simulant for the transport of chemical agent into protective ensembles. However, biological interpretations of the MIST/BRHA using methyl salicylate are not warranted.

Recommendation 4. Additional studies should be undertaken to establish absorption and transport properties of the simulant relative to the properties of the agents. *In vitro* studies using excised skin and mannequin studies (capable of simulating a bellows effect) can be used to accomplish this objective. With the appropriate consent and the oversight of a human use committee, excised human skin can be used for research. Samples can be obtained from cadavers or from surgical samples (e.g., abdominal skin, facial skin, etc.) Large differences in distributions may warrant that an alternative simulant be used.

GENERAL CONCLUSIONS AND RECOMMENDATIONS

General Conclusion 1. The first step in chemical and biological defense strategy is early detection and warning to provide situational awareness and permit steps to be taken to avoid the exposure of personnel and equipment. The complement to detection is protection. Chemical protective ensembles, as well as collective filtration systems and shelters, are used to insulate personnel from chemical and biological agents. Modeling chemical protective ensembles is a daunting task, and the Army's efforts to develop the MIST/BRHA should be commended. Modeling and simulation technologies are invaluable tools for training for operations in a chemical and biological warfare environment. They provide material and equipment design parameters and enable field commanders to integrate and interpret real-time data. However, deriving physiological endpoints from the MIST/BRHA is a complicated process that will require cooperation among the Army's scientists, as well as significant input from academia and industry.

General Recommendation 1. The development of new test methodologies should be done separately from routine ensemble testing. Once the criteria for suit performance have been established, decision points should be entered in a flow chart to reveal where additional work is needed. As of this writing, the Army has not adopted a clear approach to establishing physiologic endpoints from protective ensemble testing. However, this is an achievable goal that should be pursued to protect soldiers

General Conclusion 2. The Army should ensure better cooperation among various disciplines (i.e., chemistry, toxicology, engineering, human factors, etc.). For example, scientists in CBDCOM's toxicology division have not participated in any significant way in the development of ensemble test methods.

General Recommendation 2. More integration between the various groups and technical disciplines will be essential for the development of future testing methodologies. All relevant parties should participate in the planning phase with the objective of reaching a consensus on research objectives, design procedures, analysis, and documentation.

Technical Assessment of the Man-In-Simulant Test (MIST) Program

Report 1

ASSESSMENT OF THE U.S. ARMY CHEMICAL AND BIOLOGICAL DEFENSE COMMAND

Standing Committee on Program and Technical Review of the U.S. Army Chemical and Biological Defense Command
Board on Army Science and Technology
Commission on Engineering and Technical Systems
National Research Council

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competencies and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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Preface

This report is the first of a two-phase response to a request from the technical director of the U.S. Army Edgewood Research, Development and Engineering Center (RDEC) that the National Research Council's (NRC) U.S. Army Chemical and Biological Defense Command Standing Committee (CSC) conduct technical assessments and program reviews within the command. Specifically, the CSC was asked to conduct a technical assessment of the man-in-simulant test (MIST) program and a program review of the mass spectrometry and bioremediation programs. These programs represent a continuum of technologies designed to protect, detect, and dispose of chemical and biological weapons that soldiers may face in future combat. This report focuses on the technical assessment of the MIST program.

Members of the CSC have a wide range of expertise in chemical engineering, chemistry and biochemistry, toxicology and risk assessment, simulation and modeling, bioremediation of chemical warfare agents, physical chemistry and mass spectrometry, medicine, chemical modeling, epidemiology and industrial hazards, and military science. Members of the committee whose expertise was relevant to reviewing the MIST program were chosen to serve on the review panel. The panel met three times between October 1996 and April 1997 and heard testimony from several Army research and development experts, including representatives from the Edgewood RDEC, the U.S. Army Center for Health Promotion and Preventive Medicine, the Natick RDEC, and Dugway Proving Ground, in Utah, where the tests are conducted.

In this report, the committee documents the methodology used by the Army to test protective suit ensembles and analyze data. The committee carefully considered the best way to present its findings and organize the report, given the critical nature of the MIST program and its ramifications for Army personnel. The problem is complicated by the fact that the Edgewood RDEC is faced with operating in an environment of constrained defense budgets and reductions in military and civilian personnel. The Edgewood RDEC's workforce has been reduced by 20 percent since 1990, and the U.S. Army Material Command projects another 15 percent reduction by 2000. Funding that had been earmarked for defense research and development is also being transferred to military operations. These reductions in personnel and funding will require that priorities be precisely determined and that data be generated efficiently. To that end, the technical director of the Edgewood RDEC requested that the NRC provide expert, independent technical advice and counsel on selected aspects of the nuclear, biological, and chemical research, development, and acquisition program. The chair and the committee wish to express their gratitude for the staff assistance and support provided by the NRC. We are indebted to Bruce Braun, director, Board on Army Science and Technology; George Davatelis, study director; Jacqueline Campbell-Johnson, senior project assistant; Margo Francesco, staff associate; Alvera Gircys, financial associate; and William Holm, consultant. The work of the committee would not have been possible without these dedicated individuals. The committee also appreciates the comments and written submissions of the various groups who provided testimony and written material; Virginia Gildengorin, for reviewing the data analysis procedures; and the group of outside experts who graciously donated their time to review this report.

Francis G. Dwyer, *chair*

Standing Committee on Program and Technical Review of the U.S. Army Chemical and Biological Defense Command

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Acronyms

ANOVA	analysis of variance
BRHA	body region hazard analysis
CB	chemical and/or biological agent
CBDCOM	U.S. Army Chemical and Biological Defense Command
CPE	chemical protective ensemble
CSC	CBDCOM Standing Committee
Ct	concentration x time
CWA	chemical warfare agent
GA	nerve agent (chemical warfare agent)
GB	nerve agent (chemical warfare agent)
H or HD	mustard, blister agent (chemical warfare agent)
HDPE	high-density polyethylene
MeS	methyl salicylate
MIRANS	miniature infrared analyzers
MIST	man-in-simulant test
NBC	nuclear, biological, and chemical
NRC	National Research Council
PF	protection factor
RDEC	Research, Development and Engineering Center
VX	nerve agent (chemical warfare agent)
WBEE	whole body effective exposure